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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	4

DATE MAILED: 3/31/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

For Restriction and Election only

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ____ month(s), 3 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☒ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☒ Notice re Sequence Rules

Part II SUMMARY OF ACTION

1. ☒ Claims 1-66 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-66 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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08/599974

Amendment to Paper No. 4

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
   a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
   b. ☐ believes the named inventor or inventors to be the original and the first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
   c. ☐ acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☐ Other:

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by (37 CFR 1.41(a)).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☑ Other: There Are Unnumbered Pages After-Page 78 + Page 128.

Page 78 is a partial page at the top where the remaining text continues on the next unnumbered page. Likewise, partial (¾) sequence text on pg 128 and the remaining (¼) text is on next unnumbered page.

1. A telephone call was made to David Jackson on 3-26-97 to request an oral election to the above restriction requirement, but did not result in an election being made. **APPLICANTS EXPRESSLY REQUESTED A WRITTEN RESTRICTION.**

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 63, 66, drawn to various variant Ob receptor proteins, several point mutations and various compositions, classified in classes 530 and 514 or possibly 424, subclasses 350, 2+ and 401 respectively.

II. Claims 15-19, drawn to antigenic fragments and derivative thereto (Polymer conjugates), classified in classes 530, 424 subclasses 326+ and 185.1 respectively.

III. Claims 20-28, 34-48, 51-52, drawn to nucleic acids (NA) encoding Ob receptors (ObR), vectors ,host cells and methods of making the variant forms of the OBR, classified in classes 435 and 536, subclasses 69.1+ and 23.5 respectively.

IV. Claims 29-33, 49-50 drawn to various partial nucleic acid pieces, such as oligo's (various different oligo's), antisense and ribozymes, classified in classes 514 and 536, subclasses 44+ and 24.3+ respectively-depending on the length and use of these products.

V. Claims 53-58 drawn to antibodies to ObR and hybridoma, classified in classes 530, subclass 388.22 and 70.21.

VI. Claims 59-62, drawn to methods of measuring leptin in various samples using antibodies, classified in class 435, subclass 7.1.

VII. Claims 64-65, drawn to methods of treating weight disorders such as obesity using OB-R compositions, classified in classes 514, subclasses 2+.

The inventions are distinct, each from the other because:

Inventions Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case there are no specific claims to methods of preparing the obR using the NA, vectors and host cells of Group III; however, the obR or Group I can be made by a materially different process other than with the use of the NA, vectors and host cells of Group III such as by chemical synthesis, or the isolation from nature using various isolation/purification/chromatographic procedures. Further, the NA of Group III can be used other than to make the protein of Group I, such it their use as probes, or their use in various diagnostic procedures or in various therapeutic procedures.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups I, II, III, IV and V are directed to products that are structurally, physically and functionally distinct and determined to be patentable they would also be patentably distinct. Furthermore, these products are not required one for the other.

In a similar manner to the above, it is pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups III, VI and VII are directed to various diagnostic and therapeutic methods that require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods. Furthermore, these methods are not required one for the other.

Inventions Group I and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the protein can be used in a materially different method such as its use as a probe, to make the antibodies of Group V, or in various diagnostic or other therapeutic methods.

Inventions Group V and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in materially different method/processes as its use as in various diagnostics, immunoaffinity chromatography, as probes, or therapeutic methods.

3) IN THE EVENT APPLICANTS ELECT THE INVENTIONS OF GROUPS III OR IV, APPLICANTS ARE FURTHER REQUIRED TO ELECT AN ULTIMATE SPECIE AS FOLLOW:

This application contains claims directed to the following patentably distinct species of the claimed invention:

A) If Group I is elected, then applicants are required to elect a **single** point mutation for examination with the five variant Ob-R (selection from the mutations listed in claim 14. It is further pointed out that in view of the fact that each of the five variant forms will be examined together, inclusive of Ob-R that are made up of different part of these five receptor, and those that have different N and/or C-terminal amino acid sequences; and because there are several point mutations, only one point mutation will be examined with the remaining claims if this group is elected.

B) If Group IV is elected, then applicants may be required to elect an oligo from the various ones listed in claim 32.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic for A or B listed above, but rather claims 14 and 32 represent a Markush group for the mutant Ob-R or oligo's respectively.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be **extremely** burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5) The communication filed 8-30-96 is not fully responsive to the communication mailed 5-7-96 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report.

Since the response appears to be *bona fide*, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within a TIME LIMIT of ONE MONTH or THIRTY DAYS, whichever is longer, from the date of this letter or within the time remaining in the response period of the communication mailed 5-7-96, whichever is longer (37 CFR 1.135(c)).

No extension of this time limit may be granted under either 37 CFR 1.136(a) or (b), but the statutory period for response set in the communication mailed 5-7-96 may be extended up to a maximum of SIX (6) MONTHS under 37 CFR 1.136.

NO EXTENSION OF TIME CAN APPLY FOR COMPLIANCE WITH THE SEQUENCE RULES SINCE THE INITIAL STATEMENT ISSUED TO APPLICNATS FOR SUCH WAS 5-7-96, THUS THE POTENTIAL SIX MONTH EXTENSION PERIOD HAS ALREADY EXPIRED. Alternatively, since this is now a Rule 60 Continuation of S.N. 08/586594 in which the compliance was OK, applicants may wish to comply via the parent file of a separate disk, thato complete/proper can't be made.

5) Any inquiry concerning this communication should be directed to Garnette D. Draper at telephone number (703) 308-4232.

Garnette D. Draper

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800